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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,585	08/19/2003	David Hung	005284.00214	2937

38732 7590 03/14/2006

CYTYC CORPORATION  
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MARLBOROUGH, MA 01752

EXAMINER
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MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/642,585	<b>Applicant(s)</b> HUNG ET AL.	
	<b>Examiner</b> Charles A. Marmor, II	<b>Art Unit</b> 3736	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22,31 and 32 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22,31 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>08132003</u> . | 6) <input type="checkbox"/> Other: ____  |

### **DETAILED ACTION**

1. This Office Action is responsive to the Preliminary Amendment filed August 13, 2003. The Examiner acknowledges the cancellation of claims 23-30. Claims 1-22, 31 and 32 are pending.

#### ***Specification***

2. The disclosure is objected to because of the following informalities: At page 2, line 4, "now allowed" should read --now U.S. Patent No. 6,629,936--. Appropriate correction is required.

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

#### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-22, 31 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Hung et al. ('709). Hung et al. teach a method for differentiating a cancer risk status of milk ducts in a breast and a method of maximizing the likelihood of ductal fluid migrating to the nipple as claimed by Applicant in the independent claims including aspirating the nipple, locating at least one ductal orifice, and marking it with a marker.

6. Claims 1-6, 14, 15, 31 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Sartorius ('801). Sartorius teaches a method for differentiating a cancer risk status of milk ducts in a breast in independent claims 1 and 14 including aspirating the nipple, locating at least one ductal orifice yielding fluid, and retrieving the ductal contents from a surface of the ductal orifice. Sartorius further teaches a method of maximizing the likelihood of ductal fluid migrating to the nipple, as claimed by Applicant, by stimulating the breast and/or nipple surface with a wearable device, such as a hot towel, prior to nipple aspiration.

### ***Double Patenting***

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

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application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-32 of U.S. Patent No. 6,629,936. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent and the claims of the instant application both recite methods for differentiating a cancer risk in breast ducts comprising aspirating a nipple and locating at least one ductal orifice that yields fluid upon aspiration which indicates that the fluid-yielding nipple is at a higher risk for cancer (see particularly claims 12 and 23). The claims of the patent include additional limitations not required by the claims of the instant application. Since the claims of the instant application are anticipated by the claims of the patent, the claims are not patentably distinct.

9. Claims 1-3, 7, 9-11, 14, 16 and 18-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-16 of U.S. Patent No. 6,328,709. Although the conflicting claims are not identical, they are not patentably distinct

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from each other because the claims of the patent and the claims of the instant application both recite methods including the steps of aspirating a nipple and locating at least one ductal orifice that yields fluid upon aspiration. The claims of the instant application include an additional wherein clause that defines a fluid-yielding nipple as being at a higher risk for cancer. This appears to be an inherent property of a breast since no additional methods steps are required other than aspirating and identifying. Since a nipple yielding fluid upon aspiration appears to be inherently at a higher risk for cancer, and the claims of the instant application and the claims of the patent include the same basic method steps, it would have been obvious to one having ordinary skill in the art at the time of the invention that a fluid yielding nipple detected by the method of the claims of the patent would also be at a higher risk for cancer. Therefore, the claims are not patentably distinct.

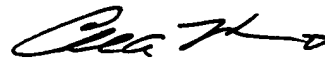
### ***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II  
Primary Examiner  
Art Unit 3736

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March 6, 2006